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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,216	10/31/2003	Martin T. Gerber	P-11611.00	1508

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EXAMINER	
LUSTUSKY, SARA	
ART UNIT	**PAPER NUMBER**
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,216	GERBER ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23, 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated December 22, 2006. Claims 4-6, 9, 15, 18-19, 21-22 and 25 have been amended. Claim 24 has been cancelled. Claims 1-23 and 25-27 are pending.

Claim Objections

In view of Applicant's amendments to the claims, the claim objections set forth in the Office Action dated July 26, 2006 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman (Patent 6251063 B1) in view of Bley (US 6592859 B1).

Silverman et al. ('063) teaches a method comprising: implanting a bulking prosthesis (337, 371) in tissue proximate to an anal sphincter (356) (as seen in Figure 19, 21 and 22) using a tubular instrument (31) (as seen in Figure 7), wherein the tissue comprises at least one of a submucosa and a musculature (202) underlying the submucosa (as seen in Figure 9 of Silverman et al.). Silverman et al. further teaches that implanting the bulking prosthesis (337, 371) comprises: penetrating a mucosa (196) proximate to the tissue with a syringe (366) needle (368) (as seen in Figures 21 and 23 of Silverman et al.) thereby forming a hole in the mucosa (196); drawing a mucosa (196) away from a musculature (201) underlying a submucosa (as seen in Figures 7 and 9); forming a pocket (227) in one of the submucosa and the musculature (201); and implanting the bulking prosthesis (337, 371) in pocket (227) (as seen in Figures 7 and 9) (as described in lines 30-37 and 64-67 of column 15 of Silverman et al.), through the syringe (366) needle (368) (as described in lines 21-26 of column 28 and 13-19 of column 29 of Silverman et al.), wherein the stability and configuration of the implant should be observed over time and may require further procedures to supplement previously formed implants (as described in lines 18-20 of column 19). While Silverman et al. teaches that said bulking prosthesis (337, 371) comprises materials including silicone, collagen and the injection of solutions which form precipitates (as described in lines 28-44 of column 27), it is not taught that the bulking prosthesis (337) enlarges after implantation.

Bley teaches a method of implanting a bulking prosthesis in the tissue of a patient, wherein said bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, wherein said bulking prosthesis

comprises a hydrogel (as described in lines 29-38 of column 2). Bley further teaches that materials such as collagen and silicone are known to break down, migrate and are often absorbed by the body (as described in lines 55-67 of column 1 and in lines 1-5 of column 2). Additionally, Bley teaches that the injection of solutions having liquids which dissipate have the disadvantage that the final size of the implant is hard to predict, often forcing a surgeon to inject either significantly more of the solution then they thought necessary and/or results in too little material being injected (as described in lines 26-53 of column 1), wherein additional injections are often required. However, using solid materials that swell after injection or implantation have an advantage in that their final size is more predictable because they swell to a size equal to that of the cavity created during the injection, thus they don't migrate away from the injection site (as described in lines 47-67 of column 6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a bulking prosthesis similar to that of Bley in a method similar to that of Silverman et al. in order to treat fecal incontinence in view of the teachings of Bley because a bulking prosthesis similar to that of Bley has a more predictable size after injection, is permanent and won't degrade or be absorbed by the body like collagen and silicone, thus eliminating the need for adjustment, repair or replacement of the implant through further injections.

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Silverman et al. (Patent 6251063 B1) and Bley (US 6592859 B1) as applied to claim 4 above, in view of Silverman et al. (Patent 6358197 B1).

The combination of Silverman et al. ('063) and Bley teaches the method of claim 4, as described above, comprising implanting a bulking prosthesis, which enlarges after implantation, in a pocket formed between the mucosa and muscle tissue proximate an anal sphincter. This combination does not teach the use of vacuum pressure.

Silverman et al. ('197) teaches a method of implanting a bulking prosthesis comprising drawing the mucosa (246, 248) away from musculature (252, 254) underlying the submucosa (256) by applying vacuum pressure (as described in lines 1-3 of the abstract and lines 53-57 of column 14) through a conduit within an instrument to the mucosa (246,248) (as seen in Figures 6 and 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method similar to that taught by the combination of Silverman et al. ('063) and Bley using vacuum pressure similar to the method taught by Silverman et al. ('197) because a vacuum allows a physician to shape the target tissue into protrusions and form implants in the protrusions which have a consistent and predetermined size and shape (as described in lines 51-54 of column 20 of Silverman et al. ('197)).

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. (Patent 6358197 B1) in view of Sawhney (PGPUB 2001/0046518 A1) and further in view of Bley (US 6592859 B1).

Silverman et al. ('197) teaches a system comprising: a needle (96,52) to make a hole through a mucosa (246) proximate to an anal sphincter (as described in lines 42-43 of column 20); a tubular instrument (96, 52) having a distal end and an opening (108) at the distal end (96b); and a pushing agent (180) to push a bulking prosthesis (337)

through the tubular instrument (96, 52) and through the hole in the mucosa (246, 248) (as described in lines 47-53 of column 17) (as seen in Figures 3, 4, 6, 20 and 26), a source of vacuum pressure (220) (as described in lines 29-31 of column 13); and a conduit (92, 232) (as described in lines 63-65 of column 4, and lines 3-5 of column 14) to deliver the vacuum pressure from the source (220) to the mucosa (246, 248) (as seen in Figure 6) (as described in lines 18-25 of column 16), wherein the conduit (92, 232) comprises a distal end with a cavity (227) at the distal end to receive the mucosa (246, 248) when the cavity (227) is positioned proximate to the mucosa (246, 248) and the vacuum pressure is delivered to the mucosa (246) (as seen in Figure 6) (as described in lines 18-25 of column 16), and wherein the tubular instrument (96, 52) comprises the needle (96, 52) (as seen in Figures 3, 4, and 6).

However, Silverman ('197) does not teach that the bulking prosthesis (337) is in a miniature state at the time of implantation and assumes an enlarged state after implantation, instead Silverman teaches that the bulking prosthesis may be a precipitate formed from an injectable solution (as described in lines 62-67 of column 17 and in lines 1-28 of column 18).

Sawhney teaches a bulking prosthesis as described above, wherein the bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation (as described in lines 4-6 of paragraph [0026]).

Bley teaches a method of implanting a bulking prosthesis in the tissue of a patient, as described above, wherein Bley further teaches that using solid materials for a bulking prosthesis has an advantage in that their final size is more predictable because they swell to a size equal to that of the cavity created during the injection, thus

they don't migrate away from the injection site (as described in lines 47-67 of column 6), as described above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a bulking prosthesis similar to that of Sawhney in a method similar to that of Silverman ('197) in order to treat fecal incontinence in view of the teachings of Bley because a bulking prosthesis similar to that of Sawhney has a more predictable size after injection, is permanent and won't degrade or be absorbed by the body like collagen and silicone, thus eliminating the need for adjustment, repair or replacement of the implant through further injections.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. (US 6338345).

Johnson et al. teaches a device comprising a bulking prosthesis comprising a hydrogel (as described in lines 31-39 of column 15) that assumes one of a miniature state and an enlarged state, and assumes a desired shape after it has expanded into the enlarged state (as described from line 54 in column 15 to line 29 of column 16), wherein the bulking prosthesis may be formed in a variety of shapes and sizes including a cylindrical, toric or rod shape, wherein optimal dimensions are patient specific (as described from line 34 in column 6 to line 18 in column 7). While Johnson et al. does not expressly teach that the bulking prosthesis may be implanted around or within the anus of a patient, this limitation in the claim is considered to be directed to the intended use of the device wherein the device of Johnson et al. is capable of performing the intended use.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6338345) as applied to claim 13, in view of Capecchi et al. (US 5489300 A).

Johnson et al. teaches a bulking prosthesis to a patient, as described above, but does not teach the use of Dacron mesh.

Capecchi et al. teaches the use of Dacron mesh to surround an implant in order to promote cellular growth around the implant (as described in lines 37-38 of column 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to surround a bulking prosthesis comprising a hydrogel similar to that of Johnson et al. with Dacron mesh similar to the prosthesis of Capecchi et al. in order to promote tissue ingrowth around the prosthesis to secure said bulking prosthesis within the implantation site (as described in lines 34-36 of column 1 of Capecchi et al.).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6338345) as applied to claim 13, in view of Silverman (Patent 6251063 B1).

Johnson et al. teaches a prosthesis to a patient, as described above, but does not teach the use of radiopaque materials.

Silverman ('063) teaches a method comprising: implanting a bulking prosthesis (337, 371) comprising a hydrogel, as described above, wherein said bulking prosthesis (337, 371) comprises radiopaque materials (as described in lines 10-13 of column 11 and in lines 15-19 of column 19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a bulking prosthesis similar to that of Johnson et al. with radiopaque materials similar to those of the bulking prosthesis of Silverman ('063) in

order to allow monitoring via x-ray or radiography of the bulking prosthesis after implantation (as described in lines 15-19 of column 19 of Silverman ('063)).

Claims 18-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6338345) in view of Silvestrini (US 5824086 A).

Johnson et al. teaches a device and method for delivering a bulking prosthesis to a patient, wherein said bulking prosthesis comprises a hydrogel (as described in lines 31-39 of column 15) that assumes one of a miniature state and an enlarged state, and assumes a desired shape after it has expanded into the enlarged state (as described from line 54 in column 15 to line 29 of column 16), wherein the bulking prosthesis may be formed in a variety of shapes and sizes including a rod shape, wherein optimal dimensions are patient specific (as described from line 34 in column 6 to line 18 in column 7), as described above, but does not teach that the bulking prosthesis has a sharpened tip nor that the bulking prosthesis is at least ten or twenty millimeters in length.

Silvestrini teaches a device comprising a rod like bulking prosthesis having a sharpened tip (as seen in Figures 4-7 and 9), wherein said bulking prosthesis comprises a hydrogel (as described in lines 26-47 of column 6), wherein said sharpened tip comprises a conical tip and wherein said bulking prosthesis assumes an enlarged state in the presence of water (as described in lines 43-50 of column 6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to form a rod shaped bulking prosthesis similar to that of Johnson et al. with a conical sharpened tip similar to that of the prosthesis of Silvestrini in order to facilitate easy implantation of the bulking prosthesis into the tissue of the patient as the bulking

prosthesis is in a miniature or "dried" state at the time of implantation, as sharpened conical tips were commonly used in the art at the time of the invention to ease surgical procedures. Furthermore, as described above, it would have been obvious to one having ordinary skill in the art at the time of the invention to form a bulking prosthesis similar to that of Johnson et al. with dimensions and configurations suitable to each patient (as described from line 34 in column 6 to line 18 in column 7 of Johnson et al.), therefore using a bulking prosthesis similar to that of Johnson et al. with a length of at least ten or twenty millimeters would have been an obvious design choice to one having ordinary skill in the art at the time of the invention to accommodate a patient requiring a bulking prosthesis of that size (for example, a very tall patient who would inherently have larger organs than a smaller or shorter patient).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Johnson et al. (US 6338345) and Silvestrini (US 5824086 A) as applied to claim 18 above, in view of Tu et al. (US 2002/0188308 A1).

The combination of Johnson et al. and Silvestrini teaches a method for implanting a rod shaped bulking prosthesis in a miniature state at the time of implantation, said bulking prosthesis having a sharpened tip proximate to the tissue of a patient, wherein said bulking prosthesis is engaged with an application device and the step of withdrawing the application device after implantation, wherein said bulking prosthesis assumes an enlarged state after implantation, as described above. However, this combination does not teach that the bulking prosthesis comprises a helical thread.

Tu et al. teaches a bulking prosthesis comprising a helical thread around the rod-like bulking prosthesis (as seen in Figures 32-34), wherein said bulking prosthesis comprises a hydrogel (as described in paragraph [0119]).

It would have been obvious to one of ordinary skill in the art to make a bulking prosthesis similar to that of the combination of Johnson et al. and Silvestrini with helical threads similar to that taught by Tu et al. in order to aid in inserting said device into the tissue of a patient and to retain said prosthesis once implanted as is a commonly known advantage of threaded or screw-like implants used in the art (as described in lines 3-5 of paragraph [0162] of Tu et al.).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (US 2002/0188308 A1) in view of Lat et al. (US 5741104 A).

Tu et al. teaches a bulking prosthesis comprising a sharpened tip and helical thread around the rod-like bulking prosthesis (as seen in Figures 32-34), wherein said bulking prosthesis comprises a hydrogel (as described in paragraph [0119]), however Tu et al. is silent as to the method of making said bulking prosthesis.

Lat et al. teaches a method of making a screw shaped device, the method comprising providing a rod-like device, forming a sharpened tip on an end of said object and machining a helical thread around said device (as described from line 66 of column 4 through line 7 of column 5).

It would have been obvious to one having ordinary skill in the art at the time of the invention to form a bulking prosthesis similar to that of Tu et al. using a method similar to that of Lat et al. as a design choice compared to other methods of forming

screw shaped devices, in order to obtain the desired bulking prosthesis shape as taught by Tu et al.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tu et al. (US 2002/0188308 A1) and Lat et al. (US 5741104 A) as applied to claim 22 above, in view of Culpen et al. (US 5542799 A).

The combination of Tu et al. and Lat et al. teaches a method of making a bulking prosthesis as described above, wherein said bulking prosthesis is implanted into the tissue of a patient wherein the bulking prosthesis is designed to resist movement away from the implantation site (as described in paragraphs [0155]-[0156]). However, this combination does not teach the formation of a slot in said prosthesis.

Culpen et al. teaches a device comprising a sharpened tip, helical threading and a slot (as seen in Figures 1 and 4) (as described in lines 40-61 of column 2).

It would have been obvious to one having ordinary skill in the art at the time of the invention to make a bulking prosthesis similar to that of the combination of Tu et al. and Lat et al. with a slot similar to that of the device taught by Culpen et al. in order to enhance the ability of the bulking prosthesis to brace against the tissue of the patient once implanted (as described in the abstract and from line 62 of column 2 to line 37 of column 3 of Culpen et al.).

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Johnson et al. (US 6338345) and Silvestrini (US 5824086 A) as applied to claim 18 above, in view of Silverman (Patent 6251063 B1).

The combination of Johnson et al. and Silvestrini teaches a method for implanting a rod shaped bulking prosthesis in a miniature state at the time of

implantation, said bulking prosthesis having a sharpened tip proximate to the tissue of a patient, wherein said bulking prosthesis is engaged with an application device and the step of withdrawing the application device after implantation, wherein said bulking prosthesis assumes an enlarged state after implantation, as described above. However, this combination does not expressly teach that the bulking prosthesis is implanted into or around an anal sphincter.

Silverman et al. ('063) teaches a method comprising: implanting a bulking prosthesis (337, 371) in tissue proximate to an anal sphincter (356) (as seen in Figure 19, 21 and 22) as described above.

It would have been obvious to one having ordinary skill in the art at the time of the invention to implant a bulking prosthesis similar to that of the combination of Johnson et al. and Silvestrini into or around the anal sphincter of a patient similar to the method of Silverman et al. in order to treat fecal incontinence.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (PBPUB 2002/0091295 A1) in view of Yeung et al. (WO 02/032321 A1).

Wilk teaches a method for implanting a bulking prosthesis comprising: implanting a rod-like bulking prosthesis (24, 52) having a sharpened tip (as seen in Figure 5), the bulking prosthesis (24, 52) engaged with an application device (14), rotating the bulking prosthesis with the application device to ensure proper positioning (as described in lines 12-15 of paragraph [0056], as seen in Figures 1A-1C); and withdrawing the application device (14) (as seen in Figures 1A-1C) comprising disengaging the bulking prosthesis from application device, as the bulking prosthesis is left in the tissue after the application device is removed (as seen in Figures 1A-1C), wherein said bulking

prosthesis is implanted into the tissue surrounding the an anal sphincter (as described in lines 9-12 of paragraph [0057]). However, Wilk does not teach that the bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation.

Yeung et al. teaches a method for implanting a bulking prosthesis comprising: implanting a rod-like bulking prosthesis (as seen in Figures 71-72) into tissue of a patient in order to provide support to a sphincter or lumen, wherein said bulking prosthesis comprises a magnetic element that is attracted to other implanted magnetic elements, or comprises a hydrogel that is in a miniature state at the time of implantation and assumes an enlarged state after implantation (as described in lines 12-16 of page 11, from line 31 of page 17 through line 6 on page 18, in lines 9-12 on page 19 and in lines 15-30 on page 28).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a swellable bulking prosthesis similar to that of Yeung et al. in a method similar to that taught by Wilk because a magnetic and swellable bulking prostheses are functionally equivalent. One of ordinary skill in the art would have expected the method of Wilk to perform equally well with either a magnetic prosthesis or a swellable bulking prosthesis as claimed in view of the teachings of Yeung et al. because a magnetic bulking prosthesis and a swellable bulking prosthesis would perform the same function of providing support to the tissue of a patient equally well.

Therefore, it would have been prima facie obvious to modify Wilk to obtain the invention as specified in claim 25 because such a modification would have been

considered a mere design consideration which fails to patentably distinguish over the prior art of Wilk.

Response to Arguments

Applicant's arguments filed December 22, 2006 on page 11 regarding claims 1-8 have been fully considered but they are not fully persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant states that the Examiner's reasoning that an injection of a solution resulting in a precipitation forming an implant may require adjustment, repair or replacement is hindsight speculation. However, it was commonly known in the art at the time of the invention that precipitates are formed on a molecule by molecule reaction from at least two agents in a solution and that the resulting material does not necessarily stick to itself, instead the precipitate falls out of solution wherever the reaction occurs. Thus it is not unreasonable that the precipitate of Silverman ('063) could comprise multiple patches of precipitate separated by fluid. Small patches of the precipitate/implant are likely to migrate away from the injection site such that follow up injections could be necessary to ensure that the implants are of the desired size. The Examiner has further provided a teaching reference to address the other types of injectable materials taught by Silverman ('063).

Applicant's arguments on page 8 of the Amendment filed December 22, 2006 with respect to the rejection(s) of claim(s) 9-12 under 35 U.S.C. 102 have been fully considered and are persuasive in view of Applicant's amendment to claim 9. Therefore, the rejection under 35 U.S.C. 102 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Silverman et al. (Patent 6358197 B1), Sawhney (PGPUB 2001/0046518 A1) and Bley (US 6592859 B1).

Applicant's arguments on pages 9 and 10 of the Amendment filed December 22, 2006 with respect to the rejection(s) of claim(s) 13-15 under 35 U.S.C. 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Johnson et al. (US 6338345).

Applicant's arguments with respect to claims 16 and 17 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments on pages 9 and 10 of the Amendment filed December 22, 2006 with respect to the rejection(s) of claim(s) 18-19 and 21 under 35 U.S.C. 102 have been fully considered and are persuasive in view of Applicant's amendment to include the limitation that said bulking prosthesis has a length of at least ten millimeters when in the enlarged state. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Johnson et al. (US 6338345) and Silvestrini (US 5824086 A). In response to Applicant's argument that Silvestrini fails to teach or suggest that said bulking prosthesis assumes an enlarged state in the presence of water, in lines 26-50 of column 6, Silvestrini teaches that the

prosthesis may comprise a hydrogel that swells when hydrated (as described in lines 43-50 of column 6).

Applicant's arguments on page 12 of the Amendment filed December 22, 2006 with respect to the rejection(s) of claim(s) 20 under 35 U.S.C. 103 have been fully considered and are persuasive in view of Applicant's amendment to include the limitation that said bulking prosthesis assumes an enlarged state in the presence of water. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Johnson et al. (US 6338345).

Applicant's arguments on page 13 of the Amendment filed December 22, 2006 with respect to the rejection(s) of claim(s) 22-24 under 35 U.S.C. 102/103 have been fully considered and are persuasive in view of Applicant's amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tu et al. (US 2002/0188308 A1), Lat et al. (US 5741104 A) and Culpen et al. (US 5542799 A).

Applicant's arguments on page 14 of the Amendment filed December 22, 2006 with respect to the rejection(s) of claim(s) 25-27 under 35 U.S.C. 102/103 have been fully considered and are persuasive in view of Applicant's amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wilk (PBPUB 2002/0091295 A1) and Yeung et al. (WO 02/032321 A1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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S.L.